

Section– II

Protocol form for research proposals to be submitted to the Institutional Animal Ethics Committee / CPCSEA, for new experiments or extensions of ongoing experiments using animals

1.	Project/Dissertation /Thesis Title	:	
2.	Principal Investigator/Research Guide/Advisor		
a.	Name	:	
b.	Designation	:	
c.	Dept/Div/ Lab	:	
d.	Telephone No	:	
e.	E-mail Id	:	
f.	Experience in Lab animal experimentation	:	
3.	List of all individuals authorized to conduct procedures under this proposal		
a.	Name	:	
b.	Designation	:	
c.	Department	:	
d.	Telephone No	:	
e.	E-mail Id	:	
f.	Experience in Lab animal experimentation	:	
4.	Funding source /Proposed Funding source with complete address (please attach the proof):		

5.	Duration of the animal experiment		
a.	Date of initiation (Proposed)	:	
b.	Date of completion (Proposed)	:	
6.	Describe details of study plan to justify the use of animals (Enclose Annexure)	:	
7.	Animals required		
a.	Species and Strain	:	
b.	Age and Weight	:	
c.	Gender	:	
d.	Number to be used (Year-wise break ups and total figures needed to be given in tabular form)	:	
e.	Number of days each animal will be housed	:	
8.	Rationale for animal usage		
a.	Why is animal usage necessary for these studies?	:	
b.	Whether similar study has been conducted on <i>in vitro</i> models? If yes, describe the leading points to justify the requirement of animal experiment	:	
c.	Why are the particular species selected?	:	
d.	Why is the estimated number of Animals essential?	:	

e.	Are similar experiments conducted in the past in your establishment?	:	
f.	If yes, justify why new experiment is required?	:	
g.	Have similar experiments been conducted by any other organization in same or other <i>in vivo</i> models? If yes, enclose the reference	:	

9. Describe the procedures in detail

- a. Describe all invasive and potentially stressful non-invasive procedures that animals will be subjected to in the course of the experiments–
- b. Furnish details of injections schedule Substances:
- c. Blood withdrawal Details
 - Volumes :
 - Sites :
- d. Radiation (dosage and schedules) :
- e. Nature of compound /Board Classification of drug/NCE: (Ex: Synthetic/Herbal etc.)

10. Does the protocol prohibit use of anesthetic or analgesic for the conduct of painful procedures? If yes, justify

11. Will survival surgery be done?

- a. Names, qualifications and experience level of personnel involved
- b. Describe post-operative care
- c. Justify if major survival surgery is to be performed more than once on a single animal.

12. Describe post-experimentation procedures.

a. Scope for Reuse	:	
b. Rehabilitation (Name and Address, where the animals are proposed to be rehabilitated)	:	
c. Describe method of Euthanasia	:	
d. Method of carcass disposal after euthanasia	:	

13. Describe animal transportation methods if extra-institutional transport is envisaged

14. Use of hazardous agents (use of recombinant DNA-based agents or potential human pathogens requires documented approval of the Institutional Biosafety Committee (IBC). For each category, the agents and the biosafety level required, appropriate therapeutic measures and the mode of disposal of contaminated food, animal wastes and carcasses must be identified)

If, your project involved use of any of the below mentioned agent, attach copy of the approval certificates of the respective agencies:

a.	Radio-nucleotides (AERB)	:	
b.	Microorganisms / Biological infectious Agents (IBSC)	:	
c.	Recombinant DNA (RCGM)	:	
d.	Any other Hazardous Chemical/Drugs	:	

Investigator’s Declaration

1. I certify that the research proposal submitted is not unnecessarily duplicative of previously reported research.
2. I certify that, I am qualified and have experience in the experimentation on animals.
3. For procedures listed under item 10, I certify that I have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described here in which may cause less pain or distress.
4. I will obtain approval from the IAEC/ CPCSEA before initiating any changes in this study.
5. I certify that performance of experiment will be initiated only upon review and approval of scientific intent by appropriate expert body (Institutional Scientific Advisory Committee/ funding agency/other body).
6. I certify that I will submit appropriate certification of review and concurrence for studies mentioned in point 14.
7. I shall maintain all the records as per format (Form D) and submit to Institutional Animal Ethics Committee (IAEC).
8. I certify that, I will not initiate the study before approval from IAEC/ CPCSEA received in writing. Further, I certify that I will follow the recommendations of IAEC/CPCSEA.
9. I certify that I will ensure the rehabilitation policies are adopted (wherever required).

Name of investigator :

Signature :

Date :

Certificate

This is to certify that the project proposal no.....entitled

“.....” submitted by Dr./Mr./Ms.

.....has been approved/ recommended by the IAEC of JSS Academy of Higher Education & Research, Mysuru in its meeting dated.....and has been sanctioned (animals)

under this proposal for a duration of next months.

Authorized by	Name Date	Signature
Chairman		
Member Secretary		
Main Nominee of CPCSEA		

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by the office).

Annexure-I

1. Title of the study :
2. Objectives :
3. Methodology :
4. Summary :

S No	Experiment	Animals						Duration
		Species	Strain	Gender	Age	Body weight	Number of animals requested	
1								
2								
3								
Total number of animals								

5. References

Annexure- II (Optional)

1. Preliminary data (*invitro / exvivo / invivo*)